WE CLAIM:

1.   A method of performing quality control in gene expression profiling on a microarray by determining a variation between a desired printing of a microarray and an actual printing of a microarray comprising:

retrieving gene expression data from one or more replicate spots;

performing a logarithmic transformation on said gene expression data from each of said one or more replicate spots;

calculating variations between said log-transformed gene expression data and an expected value for each of said one or more replicate spots;

determining a distribution of said variations for each of said one or more replicate spots;

comparing said distribution with a pre-defined distribution; and

calculating a percentage of said one or more replicate spots for which said variation exceeds a threshold.

2.   A method of performing quality control in gene expression profiling on a microarray during target sample preparation from a biological sample comprising:

generating a dynamic range of values for a target sample;

generating a dynamic range of values for internal spiked controls;

calculating a ratio between said dynamic range of values for said target sample and said dynamic range of values for internal spiked controls; and

comparing said ratio to a pre-defined value.

3.   A method of performing quality control in gene expression profiling on a microarray during labeling of target samples comprising:

generating a dynamic range of values for a labeled target sample;

generating a dynamic range of values for internal spiked controls;

generating a dynamic range of values for external spiked controls;

calculating a first ratio between said dynamic range of values for said labeled target sample and said dynamic range of values for internal spiked controls;

comparing said first ratio to a first pre-defined value;

calculating a second ratio between said dynamic range of values for internal spiked controls and said dynamic range of values for external spiked controls; and

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comparing said second ratio to a second pre-defined value.

4.   A method of performing quality control in gene expression profiling on a
microarray during hybridization of said microarray and a labeled target sample comprising:

generating a dynamic range of values for said labeled target sample;

generating a dynamic range of values for internal spiked controls;

generating a dynamic range of values for external spiked controls;

calculating a first ratio between said dynamic range of values for said labeled target
sample and said dynamic range of values for internal spiked controls;

comparing said first ratio to a first pre-defined value;

calculating a second ratio between said dynamic range of values for internal spiked
controls and said dynamic range of values for external spiked controls; and

comparing said second ratio to a second pre-defined value.

5.   The method of claim 4, wherein an internal spiked control error flag is set
when said first ratio is substantially equal to said first pre-defined value and said second ratio
is less than said second pre-defined value.

6.   The method of claim 4, wherein an external spiked control flag is set when
said first ratio is greater than said first pre-defined value and said second ratio is greater than
said second pre-defined value.

7.   A method of performing quality control in gene expression profiling on a
microarray during a background intensity check of said microarray hybridized with a labeled
target sample comprising:

retrieving intensity data from one or more replicate spots;

calculating a mean for said intensity data from said one or more replicate spots;

calculating a standard deviation for said intensity data from said one or more replicate
spots;

generating a Z-score transformation for each of said one or more replicate spots from
said intensity data from each of said one or more replicate spots, wherein said Z-score
transformation for a particular replicate spot is computed by subtracting said mean for said

intensity data from an intensity of a replicate spot and dividing by said standard deviation for said intensity data;

calculating a first percentage of spots for which the absolute value of said Z-score exceeds 1;

comparing said first percentage with a pre-defined value;

calculating a second percentage of spots for which the absolute value of said Z-score exceeds 2;

comparing said second percentage with a pre-defined value;

calculating a third percentage of spots for which the absolute value of said Z-score exceeds 3; and

comparing said third percentage with a pre-defined value.

8.   A method of performing quality control in gene expression profiling on a microarray during scanning of said microarray hybridized with a labeled target sample comprising the steps of:

slide flipping; and

grid placement.

9.   The method of claim 8, wherein said slide flipping step comprises:

retrieving intensity data for one or more replicate spots;

comparing said intensity data for each of said one or more replicate spots with a pre-defined normal intensity range; and

determining a percentage of said one or more replicate spots not within said pre-defined normal intensity range.

10.   The method of claim 8, wherein said grid placement step comprises:

retrieving intensity data from one or more replicate spots;

calculating a first mean for said intensity data from said one or more replicate spots;

calculating a standard deviation for said intensity data from said one or more replicate spots;

calculating a second mean for said intensity data from each row of oligonucleotides of said microarray;

generating a first Z-score transformation for each second mean, wherein said Z-score transformation for a particular row is computed by subtracting said first mean from said second mean for a particular row and dividing by said standard deviation for said intensity data;

calculating a third mean for each column of said microarray;

generating a second Z-score transformation for each third mean, wherein said Z-score transformation for a particular column is computed by subtracting said first mean from said third mean for a particular column and dividing by said standard deviation for said intensity data;

calculating a percentage of said first Z-score transformations and said second Z-score transformations that are greater than a pre-defined value.

11. The method of claim 10, wherein said pre-defined value is 4.

12. A method of performing quality control in gene expression profiling on a microarray during quantitation of an image of said microarray hybridized with a labeled target sample comprising:

retrieving intensity data for one or more genes each containing one or more replicate spots;

generating log-transformed intensity data by performing a logarithmic transformation on said intensity data for each of said one or more replicate spots;

retrieving a set of parameters from Imagene for each of said one or more replicate spots;

calculating a mean for said log-transformed intensity data for each of said one or more genes;

calculating a standard deviation for said log-transformed intensity data for each of said one or more genes;

calculating a CV for said log-transformed intensity data for each of said one or more genes; and

determining outlier spots when said CV is greater than a pre-defined value.

13. The method of claim 12, wherein said pre-defined value is 30.

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14. The method of claim 12, wherein said determining outlier spots comprises:

calculating one or more metrics for each of said one or more replicate spots based upon said set of parameters and said logarithmic transformation of said intensity data;

computing an outlier score; and

marking a replicate spot as an outlier if said outlier score exceeds a pre-defined value.

15. The method of claim 14, wherein said pre-defined value is 1.

16. The method of claim 14, wherein said set of parameters comprises one or more of the following:

background mode;

background standard deviation;

background mean;

signal mode;

signal standard deviation;

signal mean;

signal median;

signal area;

ignored area;

ignored median; and

a PositionOff value.

17. The method of claim 16, wherein said one or more metrics comprise one or more of the following:

a spot intensity ratio, wherein said spot intensity ratio is computed by dividing an intensity for a replicate spot by said signal median for said replicate spot;

a Z-score transformation of said background mode, wherein said Z-score transformation for said background mode is computed by subtracting said background mean from said background mode and dividing by said background standard deviation;

a signal CV, wherein said signal CV is computed by dividing said signal standard deviation by said signal mean;

a background CV, wherein said background CV is computed by dividing said background standard deviation by said background mean;

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an ignored area ratio, wherein said ignored area ratio is computed by dividing said ignored area by said signal area;

an ignored median ratio, wherein said ignored median ratio is computed by dividing said ignored median by said signal mode;

a Q signal area value, wherein said Q signal area value is equal to $e^{-|A - Ao| / Ao}$, wherein Ao is an average of said signal area for said one or more genes; and

a Z-score transformation of said PositionOff value.

18.   The method of claim 17, wherein said computing an outlier score comprises one or more of the following:

setting said outlier score to 0;

adding a first outlier value to said outlier score when said spot intensity ratio is greater than a first pre-defined value;

adding a second outlier value to said outlier score when said spot intensity ratio is less than a second pre-defined value;

adding a third outlier value to said outlier score when said Z-score transformation of said background mode is greater than a third pre-defined value;

adding a fourth outlier value to said outlier score when said signal CV is greater than a fourth pre-defined value and a logarithmic transformation of said signal mode is less than a fifth pre-defined value;

adding a fifth outlier value to said outlier score when said background CV is greater than a sixth pre-defined value and a logarithmic transformation of said signal mode is less than a seventh pre-defined value;

adding a sixth outlier value to said outlier score when said Q signal area is less than an eighth pre-defined value;

adding a seventh outlier value to said outlier score when said ignored median ratio is greater than a ninth pre-defined value; and

adding an eighth outlier value to said outlier score when said Z-score transformation of said PositionOff value is greater than a tenth pre-defined value.

19.   The method of claim 18, wherein said first outlier value is 1.

20.   The method of claim 18, wherein said first pre-defined value is 1.4.

21.　　The method of claim 18, wherein said second outlier value is 1.

22.　　The method of claim 18, wherein said second pre-defined value is 0.714.

23.　　The method of claim 18, wherein said third outlier value is 0.5.

24.　　The method of claim 18, wherein said third pre-defined value is 3.

25.　　The method of claim 18, wherein said fourth outlier value is 1.

26.　　The method of claim 18, wherein said fourth pre-defined value is 40.

27.　　The method of claim 18, wherein said fifth pre-defined value is 3.7.

28.　　The method of claim 18, wherein said fifth outlier value is 1.

29.　　The method of claim 18, wherein said sixth pre-defined value is 40.

30.　　The method of claim 18, wherein said seventh pre-defined value is 3.7.

31.　　The method of claim 18, wherein said sixth outlier value is 0.5.

32.　　The method of claim 18, wherein said eighth pre-defined value is 0.51.

33.　　The method of claim 18, wherein said seventh outlier value is 1.

34.　　The method of claim 18, wherein said ninth pre-defined value is 6.

35.　　The method of claim 18, wherein said eighth outlier value is 0.5.

36.　　The method of claim 18, wherein said tenth pre-defined value is 5.